II. REMARKS

A. Introduction

Applicants submit this Amendment in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Amendment.

Claims 1, 6, 10-11 and 15 are currently pending in the application. As indicated above, Claims 1, 6, 11 and 15 have been amended and Claim 10 has been canceled. New Claims 23-27 have also been added.

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

B. Response to Objections

1. Specification

The Examiner has objected to the specification "as failing to provide proper antecedent basis for the claimed subject matter." The Examiner contends that "[w]hile the specification discloses 'one or more of the collected waveforms', the specification does not disclose 'a plurality of waveforms'."

Applicants have accordingly amended the specification to clearly disclose "a plurality of waveforms". Applicants respectfully submit that the noted amendment merely makes explicit that which was (as is) disclosed and/or implicit in the phase "one **or more** of the collected waveforms."

Applicants have further amended the specification to provide that, in at least one embodiment, one of the collected waveforms "is broadcast into the autonomic nervous system or network." Applicants submit that the noted transmission is implicit in the present disclosure and explicitly stated in the priority provisional application.

2. Claims

The Examiner has objected to Claim 10 under 37 CFR 1.75(c),"as being of improper dependent form for failing to further limit the subject matter of a previous claim". As indicated above, Claim 10 has been canceled.

C. Response to Rejections

1. 35 U.S.C. § 112

The Examiner has rejected Claims 1, 6, 10-11 and 15 under 35 U.S.C. § 112, first paragraph, "as failing to comply with the written description requirement." The Examiner contends:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation of "regulating a plurality of functions", for which there is an absence of disclosure. The specification is enabling for affect a function of a body organ, but not a plurality of functions of a body organ.

The Examiner also contends, *inter alia*:

> ...because the specification, while being enabling for affect a function of a body organ, does not reasonably provide enablement for a plurality of functions of a body organ. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to regulate a plurality of functions the invention commensurate in scope with these claims.

Applicants have accordingly amended independent Claims 1 and 6 to reflect the regulation of "a" function of a body organ.[1]

Applicants submit that Claims 1 and 6, and Claim 15 dependent thereon, are now in accord with the mandates of 35 U.S.C. § 112. Applicants accordingly respectfully request that the objections under 35 U.S.C. § 112 be withdrawn.

[1] As indicated above, Claim 10 has been canceled.

2. 35 U.S.C. §102

The Examiner has rejected Claims 1, 6, 10-11 and 15 under 35 U.S.C. §102(b) "as being anticipated by Kennedy (U.S. 4,852,573)". The Examiner contends:

> Kennedy teaches a system and method for stimulating and regulating body organ function. The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium (33); and transmitting a first waveform signal including at least a second waveform that substantially corresponds to one or more collected waveforms to the nervous system to stimulate organ function. The system includes a source of collected waveforms (33); means for transmitting (22, 31) at least one of the collected waveforms to a body organ; and means for applying (30, 58) the transmitted waveforms to the body organ. Recording electrodes (30, 58) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the storage medium.
>
> Additionally, as to Claims 6 and 11, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ* 138.

The Examiner has also rejected Claims 1, 6, 10-11 and 15 under 35 U.S.C. § 102(e) as being anticipated by Kieval, et al. (U.S. 6,522,926). The Examiner contends:

> Kieval, et al. discloses a device to be "used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues" (col. 21, lines 11-14) by activating the baroreceptors. Kieval, et al. also discloses in column 21, lines 15-16 that "the baroreceptor activation devices described previously may also be used to provide antiarrhythmic effects". As seen in figure 3, "the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the baroreceptors 30" (col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen,* 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.,* 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.,* 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) ("Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight,* defeats the claim of anticipation."); *Transco Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int'l 1990) ("[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference").

As indicated above, Claims 6 and 11 have been amended to reflect "a storage medium for storing collected waveforms" and "a sensor for collecting waveforms from the body", respectively. The phrase "adapted to" has thus been deleted.

Applicants respectfully submit that the invention embodied in Claims 1, 6, 11 and 15, as amended, is ***not*** anticipated by Kennedy or Kieval, et al. As discussed in detail below, neither Kennedy, nor Kieval, et al. discloses "each and every limitation of the claimed invention."

a. Kennedy

Kennedy discloses an implantable electrode that can be employed to collect or acquire waveforms from the body, i.e. brain or spinal chord.[2] Although Kennedy discloses that the electrode can also be employed to transmit signals to the body, Kennedy does not teach or even suggest the step of storing a plurality of collected waveforms according to a function regulated by the collected waveforms ***or*** a source of collected waveforms that includes a storage area (or medium) for storing the collected waveforms according to the function regulated by the collected waveforms.

Kennedy also does not teach or disclose "means for selecting at least a first waveform from [the] collected waveforms, said first waveform being operative to regulate [a specific] body organ."

[2] Kennedy thus does not teach or suggest the acquisition or transmission of naturally generated waveforms from or to peripheral nerves, e.g., vagus nerve and hypoglossal nerve bundle.

b. Kieval, et al.

Kieval, et al. simply does ***not*** teach or even suggest the direct transmission of ***naturally generated waveform signals*** to the body to regulate organ function. Kieval, et al. merely teaches:

(i) the generation of "continuous control signals, periodic control signals, episodic control signals, or combinations thereof" that are specifically and solely tailored to activate a baroreceptor activation device, which, in turn, activates and/or controls baroreceptors; and

(ii) the direct transmission of the "user" generated control signals to the baroreceptor activation device.

Kieval et al. thus does ***not*** teach the direct transmission of ***naturally generated waveform signals*** to the body to regulate organ function. Moreover, the Kieval et al. generated control signals are ***not*** representative of or even related to waveform signals that are naturally generated in and collected from the body. The control signals are "user determined" and "device determinative", i.e. specifically tailored to activate a baroreceptor activation device.

Further, as noted by the Examiner, Kieval, et al. does not teach or disclose any means for storing collected waveforms.

Applicants thus respectfully submit that neither Kennedy, nor Kieval, et al. disclose "each and every limitation of the claimed invention." Applicants accordingly request that the rejections under 35 U.S.C. § 102 be withdrawn.

3. 35 U.S.C. §103

The Examiner has also rejected Claims 1, 6, 10 -11 and 15 under 35 U.S.C § 103(a) as obvious over Kieval, et al. The Examiner contends:

> Kieval, et al. discloses a device to be "used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues" (col.21, lines 11-14) by activating the baroreceptors. Kieval, et al. also discloses in column 21, lines 15-16 that "the baroreceptor activation devices described previously may also be used to provide antiarrhythmic effects". As seen in figure 3, "the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the

> baroreceptors 30" (col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.
>
> In the alternative, Kieval, et al. discloses the claimed invention except for the memory to the store waveforms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval, et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of their patient.
>
> As to Claim 6, the Applicant merely states a source of collected waveform signals indicative of a body organ functioning. Since Kieval, et al. generates a control signal as a function of the received sensor signal, then the signals are indicative of body organ functioning. Furthermore, Kieval, et al. does "directly" transmit waveform signals as disclosed in col. 7, lines 33-37.

It is well established that in determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) ("Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. § 103"). Indeed, it is the invention as a whole, including distinct functions that must be considered in obviousness determinations.

It is further well established that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or motivation to do so found either in the prior art or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992). See also *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 922 (Fed. Cir. 1984).

As stated above, Kieval et al. does not teach or even suggest the direct transmission of naturally generated waveform signals to the body to regulate organ function. Kieval et al. merely teaches the generation of "continuous control signals, periodic control signals, episodic control signals, or combinations thereof" as a "function of received sensor signals." The control signals

are specifically and solely tailored to activate a baroreceptor activation device, which, in turn, activates and/or controls baroreceptors.

Further, even if, *in arguendo*, the control signals were deemed "indicative of body organ functioning" (as contended by the Examiner), it can not be reasonably disputed that the control signals are "user determined" and "device determinative", and ***not*** representative of or even related to waveform signals that are naturally generated in the body, i.e. Applicants' collected and transmitted waveforms.

Applicants further submit that it is highly improbable that the user generated control signals would effectuate organ function if directly transmitted thereto. Indeed, it is well known in the art, that the voltage and, in many instances, amperage of such control signals are orders of magnitude greater than waveform signals (i.e. action potentials) that are naturally generated in the body.

Applicants accordingly respectfully submit that the inventions embodied in Claims 1 and 6, as amended, and Claims 11 and 15 dependant thereon, are unobvious in view of Kieval et al.

4. Double Patenting

The Examiner has additionally rejected Claims 1, 6, 10-11 and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Pat. No. 6,775,573 and Claims 1-14 of U.S. Pat. No. 6,937,903. The Examiner has also provisionally rejected Claims 1, 6, 10-11 and 15 on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-33 of Co-Pending Application No. 11/125,480 (Pub. No. 2005/0251061 A1) and Claims 1-29 of Co-pending Application No. 11/147,497 (Pub. No. 2005/0261601 A1). The Examiner contends:

> "Although the conflicting claims are not identical, they do not appear to be patentably distinct from each other since controlling respiration is achieved by regulating body organ function."

Applicants respectfully submit that Terminal Disclaimers for Pat. Nos. 6,775,573 and 6,937,903 were submitted on May 19, 2006. Further copies of the submitted Terminal Disclaimers are attached hereto.

Applicants are further submitting herewith Terminal Disclaimers for Application Nos. 11/125,480 and 11/147,497 to overcome the anticipated double-patenting rejection.

III. CONCLUSION

Applicants, having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this amendment clearly overcomes the references of record, and now submit that Claims 1, 6, 11 and 15 in the above referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,
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